



ATTORNEY'S DOCKET NO.: 2003080-0127 (SK-816-CON)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Danishefsky *et al.* Examiner: Not yet assigned
Serial No.: 10/600,012 Art Unit: 1645
Filed: June 19, 2003
For: TRIMERIC ANTIGENIC O-LINKED GLYCOPEPTIDE CONJUGATES,
METHODS OF PREPARATION AND USES THEREOF

Certificate of Mailing

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January 9, 2004

Date

Signature

Kenneth R. Maben

Typed or Printed Name of person signing certificate

Commissioner For Patents
P. O. Box 1450
Alexandria, VA 22313

Sir:

STATEMENT

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

Type of Statement

The present Information Disclosure Statement is:

- ☐ An *original* Information Disclosure Statement; or
☒ A *supplemental* Information Disclosure Statement.



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Alexandria, VA 22313

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TRANSMITTAL

Enclosed please find the following documents regarding the above-referenced matter:

1. Form PTO-1449 (2 pages);
2. Statement Filed Pursuant to the Duty of Disclosure Under 37 CFR §§1.56, 1.97 and 1.98 (6 pages);
3. Cited Art (22 references); and
4. Return Postcard.

Please charge any fees or credit any overpayments to our Deposit Account No. 03-1721.

Respectfully submitted,

Nadège M. Lagneau, Ph.D.
Reg. No. 51,908

Dated: January 9, 2004

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Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

- ☒ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
- ☐ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
 - ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
 - ☒ Before the mailing of a first Office action on the merits; or
 - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☐ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:
- ☐ Certifies that *either*:
 - ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
 - ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the

knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; or

☐ Includes herewith the fee set forth in § 1.17(p).

☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; and

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- ☒ A copy of each cited reference not indicated with an asterisk is included;
- ☐ Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status

- ☐ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

- ☐ Does not contain non-English language citations;
- ☐ Does contain non-English language citations, of which the following is a concise explanation:

[] Includes one or more translations of a non-English citation.

Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b).

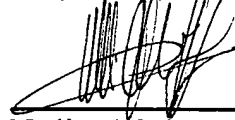
The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Respectfully submitted,



Nadège M. Lagneau, Ph.D.
Reg. No. 51,908

Dated: January 8, 2004

PATENT GROUP
CHOATE, HALL & STEWART
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Boston, Massachusetts 02109
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Form PTO-1449
(REV. 8-83)

U.S. Department of Commerce
Patent and Trademark Office

Atty. Docket:
2003080-0127
(SK-816-A)

In re Application No.
10/600,012

**SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT**

(Use several sheets if necessary)

Applicant: Danishefsky, *et al.*

Filing Date:
June 19, 2003

Group:
1645

U.S. PATENT DOCUMENTS

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
	6,090,789	Danishefsky <i>et al.</i>	July 18, 2000	514	25
	US RE38,046 E	Longenecker <i>et al.</i>	March 25, 2003	424	279.1

U.S. PATENT PUBLICATIONS

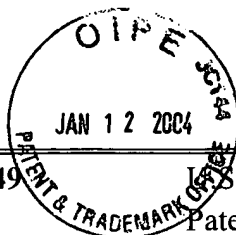
Examiner's Initials:	Publication Number:	Applicant:	Publication Date:	Class	Subclass
	US 2002/0006900	Danishefsky <i>et al.</i>	January 17, 2002	514	8
	US 2002/0038017	Danishefsky <i>et al.</i>	March 28, 2002	536	53

FOREIGN PATENT DOCUMENTS

Examiner's Initials	Document No.	Country	International Publication Date	Translation	
				Yes	No
	WO 99/15201	PCT	April 1, 1999		
	WO 01/14395 A2	PCT	March 1, 2001		
	WO 01/14395 A3	PCT	March 1, 2001		

OTHER DOCUMENTS

Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)
	Allen <i>et al.</i> , "Pursuit of optimal carbohydrate-based anticancer vaccines: preparation of a multiantigenic unimolecular glycopeptide containing the Tn, MBr1, and Lewis ^y antigens", <i>J. Am. Chem. Soc.</i> , 123 :1890-1897, 2001.
	Allen <i>et al.</i> , "A second generation synthesis of the MBr1 (Globo-H) breast tumor antigen: new application of the n-pentenyl glycoside method for achieving complex carbohydrate protein linkages", <i>Chem. Eur. J.</i> , 6 (8):1366-1375, 2000.
	Biswas <i>et al.</i> , "Construction of carbohydrate-based antitumor vaccines: synthesis of glycosyl amino acids by olefin cross-metathesis", <i>Tetrahedron Letters</i> , 43 :6107-6110, 2002.
	Blackwell <i>et al.</i> , "New approaches to olefin cross-metathesis", <i>J. Am. Chem. Soc.</i> , 122 :58-71, 2000.
	Bosse <i>et al.</i> , "Linear synthesis of the tumor-associated carbohydrate antigens Globo-H, SSEA-3, and Gb3", <i>J. Org. Chem.</i> , 67 :6659-6670, 2002.



Form PTO-1449
(REV. 8-83)

U.S. Department of Commerce
Patent and Trademark Office

Atty. Docket:
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(SK-816-A)

In re Application No.
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DISCLOSURE STATEMENT**

(Use several sheets if necessary)

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Keding *et al.*, "Hydroxynorleucine as a glycosyl acceptor is an efficient means for introducing amino acid functionality into complex carbohydrates", *Tetrahedron Letters*, **44**:3413-3416, 2003.

Kim *et al.*, "Effect of immunological adjuvant combinations on the antibody and T-cell response to vaccination with MUC1-KLH and GD3-KLH conjugates", *Vaccine*, **19**:530-537, 2001.

Kudryashov *et al.*, "Toward optimized carbohydrate-based anticancer vaccines: Epitope clustering, carrier structure, and adjuvant all influence antibody responses to lewis^y conjugates in mice", *Proc. Natl. Acad. Sci. USA*, **98**:3264-3269, 2001.

Nicolaou *et al.*, "A practical and enantioselective synthesis of glycosphingolipids and related compounds. Total synthesis of Globotriasosylceramide (Gb₃)", *J. Am. Chem. Soc.*, **110**:7910-7912, 1988.

Ragupathi *et al.*, "A Fully synthetic Globo H carbohydrate vaccine induces a focused humoral response in prostate cancer patients: a proof of principle", *Angew. Chem. Int. Ed.*, **38**(4):563-566, 1999.

Ragupathi *et al.*, "On the power of chemical synthesis: Immunological evaluation of models for multiantigenic carbohydrate-based cancer vaccines", *Proc. Natl. Acad. Sci. USA*, **99**(21):13699-13704, 2002.

Slovin *et al.*, "Carbohydrate vaccines in cancer: Immunogenicity of a fully Globo H hexasaccharide conjugate in man", *Proc. Natl. Acad. Sci. USA*, **96**:5710-5715, 1999.

Williams *et al.*, "In pursuit of an anticancer vaccine: a monomolecular construct containing multiple carbohydrate antigens", *Tetrahedron Letters*, **41**:9505-9508, 2000.

Database BIOSIS'Online! Biosciences Information Service, Philadelphia, PA, US; 22 March 2002, Kovbasnjuk Olga *et al.*, "Glycosphingolipid Gb₃ as biomarker for invasive colon carcinoma cells", *FASEB Journal*, **16**(5):A1200, 2002, Annual Meeting of Professional Research Scientists on Experimental Biology; New Orleans, LA, USA, April 20-24, 2002.

International Search Report issued for PCT application PCT/US03/22657

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.